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Food and Drug Administration
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Rockville, Maryland 20852

Re: 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications
[Docket No. 85N-0214] - - 64 Fed. Reg. 42873

On behalf of MOVA Pharmaceutical Corp., I submit the following comments in response to the Food and Drug Administration (FDA) guidance document referenced above. [I was also regulatory counsel to MOVA in MOVA Pharmaceutical Corp. v. Shalala et al., 140 F.3d 1060 (D.C. Cir. 1998).] Notice of the guidance was announced in the Federal Register on August 6, 1999. 64 Fed. Reg. 42873. As explained in detail below, certain aspects of the proposed rules are in violation of the statute and/or its stated policies.

I. Eligibility for Exclusivity Is Not Limited To The First Applicant

FDA has requested comments on its interpretation of the statute as "...allowing eligibility for exclusivity only for the **first** applicant that submits the first substantially complete ANDA with a paragraph iv certification" (emphasis added). FDA's interpretation of allowing eligibility for exclusivity only for the first applicant is inconsistent with the express terms of the statute and its stated policy. For example, in a situation where two challengers are sued, the first loses its suit, and the second challenger wins, the second challenger should be entitled to exclusivity under the terms of the statute with regard to any subsequent challengers.

Exclusivity for the second challenger in this instance is required by the express terms of the statute because the statute requires a 180-day delay of approval of an application including a paragraph iv certification if "...a previous application has been submitted..." with a paragraph IV certification. The statute is not limited to an award of exclusivity only to the "first" challenger in such a situation. If Congress had intended eligibility for exclusivity to be limited to the first applicant it would have used the words "first application" instead of "previous application" in §505(j)(5)(B)(iv) of the Act.

The stated policies of Hatch-Waxman also require eligibility of the second filer for exclusivity in

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such a situation. One of the goals of Hatch-Waxman is to make low cost generic drugs available to the public quickly. Also, given the risk of patent infringement litigation, the Act provides an incentive for generic drug applicants to file paragraph IV patent challenges for patents that may be invalid, unenforceable, or not infringed.

If the first challenger loses its litigation, the second challenger should be eligible for the exclusivity for the same policy reasons, i.e., the second challenger should be given an incentive to pursue its approval and encounter the risk of patent litigation to make low cost generic drugs available to the public quickly. Otherwise, the first challenger's loss may lead to a situation where no other challenges are pursued and no approval occurs before patent expiration because the incentive to challenge the listed patent(s) is gone. This concern was eloquently expressed in a related section of the proposed rules dealing with a situation where the first applicant loses its lawsuit:

> However, it is unreasonable to expect subsequent ANDA applicants to obtain a declaratory judgment that triggers exclusivity for a first applicant who has not provided any benefit to the public, merely because the subsequent applicant wants to avoid being blocked for the life of the patent.

64 Fed. Reg. 42873, 42876. Indeed, the second challenger may be capable of better designing around the patent or retaining more skillful attorneys to defend the patent infringement suit. The public should not be denied access to low cost generic drugs simply because the first challenger is not as skilled in pursuing paragraph IV patent challenges as subsequent potential challengers.

This is entirely consistent with other provisions of the proposed rules. In a situation where the first challenger loses its patent suit, it must amend its paragraph IV certification to a paragraph III certification under FDA's "new interpretation" of §314.94(a)(12)(vii)(A). This leaves the second challenger as the "previous applicant" under §505(j)(5)(B)(iv) and eligible for exclusivity.

There is also no support in the statute for FDA's interpretation that:

> If the first applicant subsequently withdraws its application or changes or withdraws its paragraph iv certification, either voluntarily or as a result of a settlement or defeat in patent litigation, no ANDA applicant will be eligible for 180-day exclusivity.

64 Fed. Reg. 42873, 42875. In such situations, subsequent challengers must be given the same incentive for all of the reasons set forth above.

II. First Applicant Should Have Option of Beginning Marketing If Subsequent Filer Starts Exclusivity

The proposed rules address a situation where first and second challengers are sued, and the second challenger obtains a final decision of non-infringement, invalidity or unenforceability before the

first filer obtains its final decision. In such a situation, the proposed rules provide that the first filer's exclusivity period would begin to run. FDA should give the first filer an opportunity to decide whether or not to begin marketing (assuming the application is otherwise allowable) where its exclusivity period is triggered by a court decision obtained by a subsequent challenger and it has obtained its own district court decision of invalidity, unenforceability or noninfringement. It is noted that the proposed rules include a provision for selective waiver of exclusivity under certain circumstances. However, the first applicant who has already won its case at the district court level should have the ability to take advantage of its exclusivity by marketing its own product. For example, where the second challenger obtains a final decision of invalidity during the first challenger's 30-month stay of approval under §505(j)(5)(B)(iv) and begins the first challenger's exclusivity, the first challenger should have the option to go to market with its own product.

III. Amendments To An ANDA Should Not Result In A Loss Of Exclusivity

FDA's interpretation that "...if the first applicant submits a new paragraph IV certification because, for example, it makes a formulation change requiring a supplement or an amendment to its ANDA, it may no longer be accorded first applicant status" is also contrary to the statute. 64 Fed. Reg. 42873, 42875. For example, when FDA requires a mandatory formulation change (e.g. USP change or safety ruling on an additive), this should not result in a loss of exclusivity. The statute does not leave open the possibility for conditioning exclusivity on the absence of amendments concerning formulation changes. Moreover, it is fundamentally unfair to deny the previous challenger of its right to exclusivity in a situation where a mandatory change in formulation is imposed on the applicant by FDA.

IV. Certain New Bioequivalence Studies Should Not Result In A Loss of Exclusivity

FDA's interpretation that eligibility for exclusivity requires that "the bioequivalence studies submitted in the ANDA at the time it is initially submitted must, upon review by the agency, meet the appropriate standards for approval" should not result in the loss of exclusivity under certain circumstances. For example, when FDA has not previously issued a guidance with regard to bioequivalence studies for a particular product and an additional study is required that is not in the ANDA, the applicant should not be penalized with a loss of exclusivity. It would be unfair to deny exclusivity is such situation.

V. Conclusion

For all of the reasons set forth above, the FDA's proposed rules require amendment. In the event that a hearing regarding these proposed rules or any other aspect of the 180-Day Generic Drug Exclusivity is held, I would like to participate.

Respectfully Submitted,

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